



Food and Drug Administration
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September 19, 2014

Metabiomed, Inc.
C/O Mr. Blix Winston
Submission Correspondent
ACMD Consulting, LLC
2600 Mullinix Mill Road
Mount Airy, Maryland 21771

Re: K133298
Trade/Device Name: Endo Smart, ES-100
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: August 21, 2014
Received: August 22, 2014

Dear Mr. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
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Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K133298

Device Name
Endosmart ES-100

Indications for Use (Describe)

Endo Smart ES-100 Endo Motor is indicated for use in standard endodontic procedures using rotary endodontic files and rotary endodontic drills

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. 510(k) Submitter: Metabiomed, Inc.
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5. Device Name and Classification: Trade name – Endo Smart, ES-100
Common name – Endo Motor and accessories
Classification name - Handpiece, Direct drive, AC-powered
Regulation number: 872.4200
Class: I
Product Code: EKX
6. Predicate Devices: Manufacturer : Saeshin Precision Co., Ltd.
Device : E-CUBE
510(k) Number : K111616

Manufacturer: DENTSPLY International
Device: X-Smart Easy
510(k) number: K082167

7. Device Description:

Endo Smart, Model ES-100 is a controller for micro motor and contra angle headpieces which is designed to assist dentists and dental surgeons perform standard endodontic procedures. It provides power to the hand-held micromotor and contra angle which holds the drill bit and/or file used in endodontic procedures.

Endosmart is only intended to be used with motor hand piece (manufactured by Saeshin Precision Company; part name CUBE EP) and Contra angle headpiece (Manufactured by Saeshin Precision Company; part name ACL (B) – 42P) at 16:1 gear ratio.

8. Intended Use:

Endo Smart ES-100 Endo Motor is indicated for use in standard endodontic procedures using rotary endodontic files and rotary endodontic drills.

9. Performance Testing:

Technological Characteristics

Patient contacting elements supplied with Endo Smart ES-100, the motor hand piece, contra angle headpiece and files have been previously cleared for marketing (K111616)

Biocompatibility:

The Endosmart ES-100 Endo Motor (controller unit) does not contact patients and no biocompatibility testing was performed on the controller.

Electromagnetic Compatibility and Electrical Safety

The Endo Smart ES-100 Endo Motor Conforms with IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance, IEC 60601-1-2 Medical electric equipment, General requirements for safety collateral standard electromagnetic compatibility and IEC 61000-3-2 Electromagnetic Compatibility (EMC) Part 3: Limits - Section 3: Limitations of Voltage Fluctuations.

10. Comparison table:

Characteristics	Endo Motor ES-100	ECube Endodontic motor
Manufacturer	S-Denti	Saeshin Precision Co., Ltd
510(k) number	Applied for	K111616
Class	I	I
Regulation number	872.4200	872.4200

Characteristics	Endo Motor ES-100	ECube Endodontic motor
Intended use	Endo Smart ES-100 Endo Motor is indicated for use in standard endodontic procedures using rotary endodontic files and rotary endodontic drills.	The E-CUBE is indicated for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills (Gates-Glidden)
Product Code	EKX	EKX
Use	Rx Only	Rx Only
Physical Characteristics		
Size W mm x D mm x Hmm	110 x 134 x 116.5	110 x 196 x 139
Weight g	443	582
Power V and Amps	Lithium Ion, DC 7.2V Rechargeable 2.2 Amp	AC or DC powered
AC Adapter Input Voltage	100-240 V~, 50 Hz /60Hz	100-240V, 47/63 Hz
Torque Range	0.6~6.4Ncm (Gear 16:1 basis)	0.6 to 5.2 Ncm (Gear ratio: 16:1)
Mode of Operation	Rotary	Rotary
	Auto Stop/ Forward and Reverse	Auto Stop/ Forward and Reverse
Environmental Conditions for use		
Temperature	10~40°C	N/A
Humidity	30~75%	N/A
Transport and Storage conditions		
Temperature	-20~70°C	N/A
Relative Humidity	0~95%	N/A
Accessories		
Micro motor Manufacturer	SAESHIN PRECISION CO., Ltd.	SAESHIN PRECISION CO., Ltd
Model	CUBE EP	CUBE EP
Contra Angle	ACL(B)-42EP 16:1	ACL(B)-42EP 16:1

Characteristics	Endo Motor ES-100	ECube Endodontic motor
Display	LCD	LCD
Protection type and level against electric shock	Class IIa /Type B applied part, internal powered device	Class I/ Type BF
Foot Pedal	None	Yes
Performance Testing		
	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) / EN 60601-1: 2006	IEC 60601-1
	IEC 60601-1-2	IEC 60601-2
	Software Validation FDA Software Validation Guidance	

11. Substantial Equivalence

Endo Smart ES-100 has an intended use similar to the predicate devices, and similar features and technological characteristics as X-Smart Easy (K092614) and E-CUBE (K111616). Additionally, ES-100 used identical Micro Motor, Contra Angle hand piece and files used by E-Cube and ES-100 conforms to the electromagnetic compatibility and electrical safety standards that were used to test safety and efficacy of predicate devices.

12. Conclusion

Based on performance testing and product description Metabiomed Inc. concludes that Endosmart ES-100 is substantially equivalent to X-Smart Easy Endo motor and ECube.